

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SAN ROCCO THERAPEUTICS, LLC,

Plaintiff,

v.

BLUEBIRD BIO, INC. and THIRD ROCK
VENTURES, LLC,

Defendants.

C.A. No. 21-1478-RGA

MEMORANDUM

Before me is Defendants’ motion to dismiss Plaintiff’s second amended complaint because of lack of standing and because of Plaintiff’s waiver of right to sue. (D.I. 44). In the alternative, Defendants move to stay proceedings and compel arbitration. (D.I. 44). Plaintiff filed a cross motion to join Memorial Sloan Kettering Cancer Center (“MSK”) in the event that the Court finds that MSK is a necessary party to this case. (D.I. 55). I have considered the parties’ briefing. (D.I. 45, 56, 63, 66, 71, 72, 73).

I. BACKGROUND

Plaintiff San Rocco Therapeutics (“SRT”) is a biopharmaceutical company that develops recombinant vectors used in gene therapies for the severe genetic diseases Beta Thalassemia and Sickle Cell. (D.I. 39 at ¶¶ 3-7; D.I. 45 at 4). Defendant bluebird is a biotechnology company that also develops gene therapies involving recombinant vectors. (D.I. 39 at ¶ 8; D.I. 45 at 4). Defendant Third Rock Ventures is a venture capital firm and a past shareholder of bluebird. (D.I. 39 at ¶ 9; D.I. 45 at 4).

This litigation involves two patents-in-suit, U.S. Patent Nos. 7,541,179 and 8,058,061. MSK is the assignee of the patents-in-suit. (D.I. 39 at ¶¶14, 16; D.I. 45 at 1 n.1). In a 2005 Exclusive License Agreement (the “2005 Agreement”), MSK (through its affiliate Sloan-Kettering Institute for Cancer Research (“SKI”)) granted to SRT an “exclusive worldwide right and license” to “commercially develop” a drug practicing the patents-in-suit. (D.I. 45-1, Ex. A at § 2.1). The 2005 Agreement was terminated in 2011. (D.I. 45-1, Ex. B at 1).

In 2017, SRT sued bluebird and SKI in the Supreme Court of the State of New York, in an action captioned *Errant Gene Therapeutics, LLC v. Sloan-Kettering Institute for Cancer Research*, No. 150865/2017 (the “New York Litigation”). In 2019, SRT sued Third Rock and an individual defendant in the Superior Court for the Commonwealth of Massachusetts, in an action captioned *Errant Gene Therapeutics, LLC v. Third Rock Ventures, LLC*, No. 19-1832 (the “Massachusetts Litigation”). A trial commenced in the New York Litigation on October 29, 2020. On November 2, 2020, prior to the conclusion of the trial, SRT, MSK/SKI, and bluebird entered into the Confidential Settlement Agreement (“2020 Agreement”). (D.I. 45-1, Ex. C at 1). The 2020 Agreement settled both the New York Litigation and the Massachusetts Litigation. (D.I. 45-1, Ex. C at 1).

The 2020 Agreement contains a license provision, which states in relevant part:

To resolve any and all disputes between the Parties related to the Dispute, MSK shall:

a. Give EGT [SRT] an exclusive, royalty-free commercial license to the intellectual property licensed in the 2005 Agreement;

...

[e].¹ MSK agrees to give give [sic] EGT [SRT] an exclusive, royalty-free commercial license to any intellectual property, whether owned in whole by MSK or jointly with any other party, or licensed to MSK, to the extent MSK has the rights to do so, and for which developing making, having made, using, importing, selling or offering to sell the

¹ Due to an error, the 2020 Agreement labels this item “a.” Following the parties, the Court refers to this provision as “2.[e].”

TNS9.3.55 vector or any modified or related lentiviral vector would be or could be infringed.

(D.I. 45-1, Ex. C at 2). The parties propose opposing interpretations of the grant of an “exclusive, royalty-free commercial license” in paragraphs 2.a and 2.[e]. Plaintiff maintains that 2.a of the 2020 Agreement gave Plaintiff an “exclusive (worldwide) commercial license,” which includes “the right to exclude others from making, having made, using, importing, selling, or offering for sale in the United States any lentiviral vector, gene therapy treatment, or drug product that is covered by a valid claim of the Patents-in-Suit, which are the intellectual property licensed in the 2005 Agreement.” (D.I. 39 at ¶¶ 18-20). Defendants reject these arguments as “without any support.” (D.I. 45 at 10-11). Defendants deny that the 2020 Agreement grants Plaintiff any right to exclude others from practicing the patents-in-suit, to enforce the patents against infringers, or to sublicense the patents. (D.I. 45 at 10-11). Defendants argue that once Plaintiff’s patent rights are properly identified, Plaintiff will lack constitutional and statutory standing to sue. (D.I. 45 at 9-13). Consequently, Defendants move to dismiss under Rule 12(b)(1) for lack of constitutional standing and under Rule 12(b)(6) for lack of statutory standing. (D.I. 44; D.I. 45 at 9, 12-13).

The 2020 Agreement contains a release provision, which states in relevant part:

The Parties exchange mutual general releases which shall include, without limitation, all claims, both at law and in equity, accrued or unaccrued, known or unknown, suspected or unsuspected that relate to or arise out of (i) the 2005 Agreement, (ii) the 2011 Agreement, (iii) the Dispute, (iv) the actions of any of the Parties or any Affiliate of any Party leading to the execution of the 2005 Agreement or the 2011 Agreement[.] . . .

EGT [SRT] and [related entities] . . . fully, finally and forever release, relinquish, acquit and discharge MSK and all of MSK’s past and present partners and associates, principals, shareholders, members, directors, officers, representatives, predecessors, successors, partnerships, corporations, heirs, executors, administrators, assigns, insurers, reinsurers, employees and attorneys (collectively the “**MSK Releasees**”) from and against any and all claims, causes of action, demands, disputes, suits, debts, dues, liabilities, . . . or any other theory of recovery, in law, admiralty or equity, whether known or unknown, suspected or unsuspected, asserted or unasserted, foreseen or unforeseen, that [SRT] may have, ever had or now has against the MSK Releasees or any of them, for upon or by

reason of any cause or thing, from the beginning of the world to the Parties' execution of this Confidential Settlement Agreement.

(D.I. 45-1, Ex. C at ¶ 5). The parties disagree about the scope of this release. Defendants claim that bluebird was developing treatments using the BB305 vector prior to and as of the 2020 Agreement. (D.I. 45 at 16-17). They claim that SRT had "clear knowledge" at the time of the 2020 Agreement that bluebird was "developing its gene therapy treatments using a lentiviral vector," and thus that the BB305 vector was a "cause or thing" existing prior to the agreement (D.I. 45 at 17-18). Consequently, Defendants argue, SRT waived its right to sue bluebird for infringement relating to the BB305 vector. (*Id.*). Defendants also argue that Third Rock is released from liability. (D.I. 45 at 18 n.13.). Plaintiff disagrees, arguing that the release provision is not applicable to its claims. (D.I. 56 at 18-20). Plaintiff disagrees with Defendants both on the timing of bluebird's use of the BB305 vector and on the construal of the release provision. (D.I. 56 at 19-21). Finally, MSK, which Plaintiff moves to join as a plaintiff to this action, maintains that Plaintiff has waived the very claims against Defendants that Plaintiff is asserting. (D.I. 45-1, Ex. F at 1).

The 2020 Agreement contains an arbitration clause, which states in relevant part:

The Parties [SRT, MSK, and bluebird] shall make all reasonable efforts to resolve any dispute concerning this Confidential Settlement Agreement, its construction, or its actual or alleged breach, by face-to-face negotiations between senior executives. Should such negotiation fail to resolve the matter, as defined by either party sending written notice to the other party of an impasse after at least one face-to-face negotiation meeting among senior executives of the parties, the matter shall be finally decided by David Ichel of X-Dispute, LLC or, if Mr. Ichel is not available, three (3) neutral arbitrators (the "Tribunal") seated in New York, New York under the AAA Arbitration Rules (the "Rules").

(D.I. 45-1, Ex. C, ¶ 7). Defendants argue that the disputes regarding the license provision and the release provision should be sent to arbitration if the Court does not dismiss the case. (D.I. 45 at

19-20). Plaintiff argues that these disputes are outside the scope of the arbitration agreement. (D.I. 56 at 22-25).

II. LEGAL STANDARDS

A. Rule 12(b)(1)

Federal Rule of Civil Procedure 12(b)(1) permits the dismissal of an action for lack of subject matter jurisdiction. A Rule 12(b)(1) motion may be treated as either a facial or factual challenge to the court's subject matter jurisdiction. *See Davis v. Wells Fargo*, 824 F.3d 333, 346 (3d Cir. 2016). A facial attack contests the sufficiency of the pleadings, whereas a factual attack contests the sufficiency of jurisdictional facts. *See Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015). When considering a facial attack, the court accepts the plaintiff's well-pleaded factual allegations as true and draws all reasonable inferences from those allegations in the plaintiff's favor. *See In re Horizon Healthcare Servs. Inc. Data Breach Litig.*, 846 F.3d 625, 633 (3d Cir. 2017). When reviewing a factual attack, the court may weigh and consider evidence outside the pleadings. *See Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). The party asserting subject matter jurisdiction bears "the burden of proof that jurisdiction does in fact exist." *Id.*

Defendants move to dismiss this case under Rule 12(b)(1) for lack of constitutional standing. (D.I. 44). Constitutional standing to sue is a threshold requirement in every federal case. *Warth v. Seldin*, 422 U.S. 490, 498 (1975). "[T]he touchstone of constitutional standing in a patent infringement suit is whether a party can establish that it has an exclusionary right to suffer legal injury." *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010). The Patent Act "does not limit the right to sue to only patent owners and assignees" and those with "all substantial rights in the patent," but extends the right to sue to an "exclusive licensee." *Id.* at

1264. “To be an exclusive licensee for standing purposes, a party must have received, not only the right to practice the invention within a given territory, but also the patentee’s express or implied promise that others shall be excluded from practicing the invention within that territory as well.” *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995). An exclusive licensee with “exclusionary rights,” but lacking all substantial rights, “cannot bring suit in its own name,” though “it may still bring suit along with the patentee.” *Lone Star Silicon Innovations LLC v. Nanya Tech. Corp. USA*, 925 F.3d 1225, 1229 (Fed. Cir. 2019) (citation omitted). In contrast, “without granting [licensee] the right to enforce the patent, either explicitly or impliedly, the document conveys no more than a bare license” that does not entitle the licensee to bring suit, even if the patentee joins. *Fieldturf, Inc. v. Sw. Recreational Indus., Inc.*, 357 F.3d 1266, 1269 (Fed. Cir. 2004). A defendant may move to dismiss suits for lack of constitutional standing pursuant to Rule 12(b)(1). *Lone Star*, 925 F.3d at 1235.

B. Rule 12(b)(6)

When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept the complaint’s factual allegations as true. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). Rule 8(a) requires “a short and plain statement of the claim showing that the pleader is entitled to relief.” *Id.* at 555. The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a “formulaic recitation” of the claim elements. *Id.* Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Defendants move to dismiss this case under Rule 12(b)(6) for lack of statutory standing. (D.I. 44; D.I. 45 at 12-13). Only a “patentee” or one of the “successors in title” may bring a patent infringement suit in their own name. 35 U.S.C. § 281. A party to a licensing agreement

has statutory standing if “the agreement transferred all substantial rights to the patents” to the party. *Lone Star*, 925 F.3d at 1229. Unless it shows that it possesses all substantial rights, a party “cannot bring suit in its own name.” *Id.* A defendant may move to dismiss such suits under Rule 12(b)(6). *Lone Star*, 925 F.3d at 1235. However, an exclusive licensee who lacks statutory standing may, in certain cases, join the patentee or successor in title as an involuntary plaintiff. *Abbott Lab’ys v. Diamedix Corp.*, 47 F.3d 1128, 1133 (Fed. Cir. 1995).

C. Federal Arbitration Act

The Federal Arbitration Act (“FAA”) mandates enforcement of valid, written arbitration provisions. *See* 9 U.S.C. § 2; *Cir. City Stores, Inc. v. Adams*, 532 U.S. 105, 111 (2001). To determine whether a party agreed to submit a dispute to arbitration, a court must consider “(1) whether there is a valid agreement to arbitrate between the parties and, if so, (2) whether the merits-based dispute in question falls within the scope of that valid agreement.” *Century Indem. Co. v. Certain Underwriters at Lloyd’s, London*, 584 F.3d 513, 527 (3d Cir. 2009); *see also Flintkote Co. v. Aviva PLC*, 769 F.3d 215, 220 (3d Cir. 2014). If a district court is satisfied that the issue in dispute should go to arbitration based on an arbitration agreement, then the court must submit the issue to arbitration upon motion by one of the parties. 9 U.S.C. § 3.

Under the FAA, a court should generally resolve doubts as to the scope of an arbitration clause in favor of arbitration. *Moses H. Cone Mem’l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24-25 (1983). This policy favoring arbitration stops short of favoring arbitration of arbitrability. “It is presumed that courts must decide questions of arbitrability unless the parties clearly and unmistakably provide otherwise. . . . The burden of overcoming the presumption is onerous, as it requires express contractual language unambiguously delegating the question of arbitrability to the arbitrator.” *Opalinski v. Robert Half Int’l, Inc.*, 761 F.3d 326, 335 (3d Cir. 2014) (internal

quotations marks and citation omitted); *see also First Options of Chi., Inc. v. Kaplan*, 514 U.S. 938, 944 (1995).

III. DISCUSSION

Defendants request that the Court compel arbitration in the alternative to dismissing this case. (D.I. 44, D.I. 45 at 3). If any issues in this dispute are arbitrable, the Court must submit those issues to arbitration, and the Court must not decide them. The issues in dispute here implicate both alternatives in Defendants' motion, i.e., whether they provide a basis for dismissal and whether the parties agreed to arbitrate them. For this reason, the Court will address the arbitrability issue first.

The first round of briefing disclosed the course of related litigation in New York based on the 2020 Agreement. *See San Rocco Therapeutics, LLC v. Memorial Sloan-Kettering Cancer Center*, Case No. 21-cv-08206 (S.D.N.Y. filed Oct. 5, 2021) (D.I. 36). In that case, Defendant argues that the question of arbitrability was delegated to the arbitrator. But Defendants in this case had not argued that. The Court asked the parties to address that question. (D.I. 70). Plaintiff maintains that the Court should decide the issue of arbitrability, and Plaintiff argues that Defendants have waived argument on the issue. (D.I. 56 at 22; D.I. 72 at 1-2). The Court agrees that Defendants have waived argument on the issue by not raising it in their opening brief. *See Laborers' Int'l Union v. Foster Wheeler Corp.*, 26 F.3d 375, 398 (3d Cir. 1994). Defendants have not disputed Plaintiff's assertion that Defendants have waived their right to raise the issue. (D.I. 63 at 14-15; D.I. 71 at 1-3). The Court need not launch its own inquiry into the question, but may rely on the parties' own posture on the issue.² *See CardioNet, Inc. v. Cigna Health*

² Defendants' opening brief makes no argument regarding who decides arbitrability. (*See* D.I. 45 at 19-20). They asked the Court to do that. Thus, that is the waiver. After the Court raised the issue, Defendants maintain that the arbitrator should decide arbitrability (D.I. 71 at 3). However,

Corp., 751 F.3d 165, 171-72 (3d Cir. 2014) (holding that, because parties did not raise it on appeal, the issue of who decides arbitrability need not be reviewed *sua sponte*); *Gov't Emps. Ins. Co. v. Stelton Radiology Corp.*, 2022 WL 1486116, at *4 (D.N.J. May 11, 2022) (“No party having contended otherwise, I assume without further analysis that the Agreement leaves the question of arbitrability to judicial determination.”). For these reasons, the Court will assume that it has the authority to decide the issue of arbitrability.

The parties do not dispute that the 2020 Agreement contains a valid arbitration clause. The parties dispute the scope of the arbitration clause in the 2020 Agreement. Defendants argue that the present disputes regarding the license and release provisions are arbitrable. (D.I. 45-1 at 19-20; 63 at 14-15). Plaintiff denies this, arguing that the present dispute is outside the scope of the arbitration clause. (D.I. 56 at 22-25).

The arbitration clause expressly states that “any dispute concerning this Confidential Settlement Agreement, its construction, or its actual or alleged breach . . . shall be finally decided by” an arbitrator. (D.I. 45-1, Ex. C, ¶ 7). Here, there is a genuine dispute about the construction of the license and release provisions. First, the parties disagree on what the “exclusive, royalty-free commercial license” means. Plaintiff asserts, and Defendants deny, that Plaintiff was granted a license with exclusionary rights and not merely a bare license. Whether Plaintiff has constitutional standing depends on which interpretation is right. Plaintiff asserts, and Defendants deny, that the license provision transferred all substantial rights in the patents-in-suit to Plaintiff.

at the same time, Defendants recognize that the application of the AAA rules “arguably is conditional” – applicable only if the preferred arbitrator (Mr. Ichel) is unavailable. (*Id.*). Defendants perhaps assume that an arbitrator is not required to decide arbitrability, because they argue that, “in the first instance,” the Court has the authority to dismiss this case based on the Court’s own construction of the 2020 Agreement, without first submitting the arbitrability issue to an arbitrator. (*Id.*).

Whether Plaintiff has statutory standing depends on which interpretation is right. Second, Defendants assert, and Plaintiff denies, that Plaintiff waived its right to bring this infringement suit in the 2020 Agreement. This disagreement turns on the construction of the release provision because the parties accuse each other of “misreading” (D.I. 66 at 2) or “mischaracteriz[ing] the language of” (D.I. 63 at 9) the release provision. Whose interpretation of the contract is right on these issues? Since the 2020 Agreement committed questions regarding contract construction to the arbitrator, it is for the arbitrator, not the Court, to say. Because it falls within the scope of a valid arbitration agreement, these interpretive disagreements must be submitted to arbitration. For the same reason, the Court cannot grant a motion to dismiss that depends on the resolution of an arbitrable dispute.

Plaintiff objects that disputes regarding the license and release provisions are not arbitrable because the arbitration clause is “narrow.” (D.I. 56 at 22-23). But even assuming for the sake of argument that the clause does not submit to arbitration “all disputes and controversies of every kind and nature” arising out of the agreement, *see Griswold v. Coventry First LLC*, 762 F.3d 264, 271 n.5 (3d Cir. 2014), the present dispute falls squarely within the narrow category of a dispute regarding “construction” of the 2020 Agreement. Plaintiff does not address this point. For at least this reason, Plaintiff’s argument fails.

Plaintiff also argues that the Court, not an arbitrator, must determine standing. (D.I. 56 at 25). This observation is true but irrelevant. The arbitrator here is called on to interpret a contract, not to determine standing. The Court may consider the arbitrator’s findings because the court may “consider evidence outside the pleadings” in its evaluation of a factual attack under Rule 12(b)(1). *See Gould Elecs. Inc. v. United States*, 220 F.3d at 176. “In determining whether a motion to dismiss should be granted,” the Court “may find it necessary to inquire into


jurisdictional facts that are disputed.” *See Rocovich v. United States*, 933 F.2d 991, 993 (Fed. Cir. 1991). And because a proper interpretation of the license provision is also required for determining whether the Plaintiff received all substantial rights to the patents-in-suit, the arbitrator’s determination is also required for determining whether Plaintiff has statutory standing, and thus whether to grant Defendants’ Rule 12(b)(6) motion to dismiss.

Plaintiff cites two cases in favor of denying arbitration. (D.I. 56 at 25). Both cases are inapposite. First, though “[w]hether a plaintiff has standing to sue is a matter of law to be determined by the court,” *EMC Corp. v. Pure Storage, Inc.*, 165 F. Supp. 3d 170, 174 (D. Del. 2016), the question submitted to the arbitrator here is a threshold issue related to standing, not the standing question itself. Second, a district court cannot compel arbitration on the substance of a plaintiff’s patent infringement claim if a plaintiff lacks standing. *Golden Eagle USA, LLC v. Consol. Indus. Corp.*, 161 F. App’x 949, 950 (Fed. Cir. 2006). Here, unlike in *Golden Eagle*, I am not forgoing or overlooking the standing inquiry, but compelling arbitration as part of it. And at least at this stage, I am not compelling arbitration of Plaintiff’s patent infringement claims.

For the above reasons, I will stay the case pending resolution of the threshold interpretive disputes pertaining to the license and release provisions. Defendants seek dismissal based on their proposed interpretation of the licensing and release provisions in the 2020 Agreement. (D.I. 45 at 9-19). Because I have provided no construction of those provisions, I will deny Defendants’ motion to dismiss without prejudice. Similarly, because Plaintiff’s cross-motion to join the patent owner depends on a particular interpretation of the 2020 Agreement, I will deny Plaintiff’s motion without prejudice.

IV. CONCLUSION

I will grant in part Defendants' Motion to Compel Arbitration and Stay the Proceedings. (D.I. 44). I will stay the case pending the determination of an arbitrator regarding interpretation of the license and release provisions. I will deny without prejudice Defendants' request to dismiss this case. I will also deny without prejudice Plaintiff's Cross-Motion to Join the Patent Owner Under Fed. R. Civ. P. 19 and Amend the Complaint. (D.I. 55).


United States District Court